ANIMAL HEALTH INSTITUTE

Representing manufacturers of animal health products

Alexander S. Mathews
President and CEO

December 14, 2004

Division of Dockets Management
U.S. Food and Drug Administration
HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004D-0440 – Draft Guidance for Industry on Computerized Systems Used in Clinical Trials

The ANIMAL HEALTH INSTITUTE ("AHI") submits these comments to the Draft Guidance for Industry, "Computerized Systems Used in Clinical Trials," published by FDA in the *Federal Register* on October 4, 2004.

AHI is the national trade association representing manufacturers of animal health products – the pharmaceuticals, vaccines and feed additives used in modern food production, and the medicines that keep livestock and pets healthy.

We provide the following comments for your consideration prior to the finalization of this document.

Sincerely,

Alexander S. Mathews

Enclosure

2004D-0440 C3

1325 G Street, NW ■ Suite 700 ■ Washington, D.C. 20005-3104
Telephone (202) 637-2440 ■ Fax (202) 393-1667
www.ahi.org

Comment Form

				Date	Document
				December 14, 2004	Computerized Systems Used in Clinical Trials
Commenter	**Section**	**Paragraph Figure/ Table Line No.**	**Proposed Change**	**Comment/ Rationale**	
AHI	III. 1.	Lines 76-77	Propose adding "if known at the time of protocol development." We recommend that each study protocol reference the computerized system documentation that will be used.	It is likely that decisions regarding the archiving of data will not be know during the protocol development stage, particularly with the new paper-based solutions outlined in the new guidance document. As written, this would add unnecessary volume to the protocol and a burden on the Sponsor.	
AHI	III. 3.	83-84	...are satisfied as appropiate at this stage in the process (E.G.data are recoreded in the correct units, keep study blinded)...	It may be more appropriate to check for certain errors at a later stage in the process.	
AHI	III. 6.	95-96	Except when persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to perform their regulated activities then the paper is considered the source document	Per the August 2003 Guidance for Industry: Part 11, Electronic Records; Electronic Signatures – Scope and Application lines 166 – 171. "On the other hand, when persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to perform their regulated activities, PDA would generally not consider persons to be 'using electronic records in lieu of paper records' under § § 11.2(a) and 11.2(b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11." For example, milking machines collect the data; the data is printed out and signed. The paper would be the original.	
AHI	III.9.	Lines 112-114	Propose changing to "...security measures be in place to prevent unauthorized **write** access to the data"	Unauthorized *write* access needs to be prevented to ensure authenticity and integrity of the data. The *sponsor* will probably want to prevent unauthorized *read* access as well, but this should not be of concern to the Agency.	
AHI	VI. C.	Lines 233-235	Proposed adding bolded phrase: **"In systems that implement computer-generated, time-stamped electronic audit trails,** we recommend that controls be put in place to ensure that the system's date and time are correct. The ability to change the date or time should be limited to authorized personnel..."	It should be clarified that this section applies to systems that use computer-generated, time-stamped electronic audit trails. The only way to achieve this on a Windows system, for example, would be to make the users logon as non-administrative users and to install a system policy that prohibits normal users from changing the date and time.	

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AHI	VII. A.	Line 258	. . automatically enter ***study*** data	Other data like enterers initials could be automatically entered without impacting the study data. Additional information such as audit trail information may be preferable to hand entered data.
AHI	VIII.	Line 297	Remove or clarify "Device Checks"	Reflects old model of terminals directly connected to dedicated systems and not current apps run over secure networks and internet connections.
AHI	VIII.	Lines 303–305	Remove "browsed, queried or reported"	Data often queried, browsed or reported for maintenance, debugging or presentation purposes using systems other than the controlled system (example, using Crystal Reports to report on clinical data in Oracle). However, protections against altering the data (read-only accounts, etc.) coupled with audit trailing can protect data's integrity.
AHI	IX.	Lines 329–331	Change wording from "and the relationships among hardware, software, and physical environment" to "the relevant operating instructions and user manuals."	Providing system hardware configuration for systems housed at the sponsor but connected to by the site(s) seems unnecessary since the configuration may change over time and the site's personnel may not understand the information The system's owner seems the logical choice for maintaining the system's software and hardware configuration documents.
AHI	IX.	Lines 350-352	"If validation is required, FDA may ask to see the regulated company's documentation that demonstrates software validation. The study sponsor is responsible for making any such documentation available if requested at the time of inspection at the site where software is ~~used~~ **installed**."	If the system resides at the sponsor's site and is used remotely from the investigator's site — *i.e.*, the software is used remotely and does not physically reside within a system at the investigator's site, it is not reasonable to expect that a copy of the system validation report be available at each investigator's site. This wording should be clarified.